DEC 16 2013

510 (k) SUMMARY

1 OWNER / SUBMITTER INFORMATION:

Owner: Mikron Makina Sanayi Ticaret Ltd Sti
Address: İ.O.S.B. Ağaç İşleri San. Sit. 1372. Sokak No:31 06370 Ivedik / Ankara / Turkey
Phone Number: 90 312 3951700
Fax Number:
Contact Person: Omar Diker / Ohltech Inc. / 410 885-9978 / omar@ohltech.com
Date Prepared: 12/16/2013

2 DEVICE INFORMATION:

Common or Usual Name:.Spinal Fixation System
Proposed Proprietary or Trade Name: Mikron Spinal Fixation System
Classification Name: 21 CFR 888.3070 Pedicle Screw Spinal System
Class Designation: Class II
Product Codes : MNH, MNI

3 SUBSTANTIAL EQUIVALENCE:

Mikron Spinal Fixation System is substantially equivalent to the legally marketed in function, intended use, material and design to 4S Spinal System (K063708) and Optima Spinal System (K031585).

4 DEVICE DESCRIPTION:

Mikron Spinal Fixation System is a top-loading multiple component, posterior spinal fixation system consisting of polyaxial pedicle screws, rods, and set screws. The Mikron Spinal Fixation System will allow surgeons to build a spinal implant construction to stabilize and promote spinal fusion and it functions to build a spinal implant construct to stabilize and promote spinal fusion. The Mikron Spinal Fixation System components are supplied non-sterile, single use and fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136-11. Various sizes of these components are available.

5 INDICATION OF USE:

The MSFX Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T1 to S2): severe spondylothesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylothesis with objective evidence of neurologic impairment; fracture; dislocation; spinal stenosis; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

6 STATEMENT OF TECHNICAL COMPARISON:

The summary of the technological characteristics of the Mikron Spinal Fixation System compared to the predicate devices are as follows:

6.1 Material

The Mikron Spinal Fixation System and predicate devices are fabricated of the same material; which is titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136-11.

6.2 Design

The Mikron Spinal Fixation System and predicate devices have similarly designed and sized components which are polyaxial screws, cylindrical longitudinal rods, and set screws. Also, the Mikron Spinal Fixation System and predicate devices have similar top-loading interconnection mechanism.

6.3 Function

The Mikron Spinal Fixation System and predicate devices have similar functions which are acting as a spinal implant construct to stabilize and promote spinal fusion.

6.4 Level of Attachment

Levels of fixation of the Mikron Spinal Fixation System are for the thoracic, lumbar and sacral spine. Similarly predicate devices are also intended to attach to spinal segment of thoracic, lumbar and sacral.

6.5 Intended Use

The Mikron Spinal Fixation System is indicated for the same intended uses as the predicate devices.

6.6 Sterility

The Mikron Spinal Fixation System is supplied in non-sterile and single use. Similarly the predicate devices are supplied non-sterile and single use.

7 NON-CLINICAL PERFORMANCE TESTING:

Test Name	Standard Applied
Determining Torsional Properties of Metallic Bone Screws	ASTM F 543
Flexion-Extension Test of Subassembly	ASTM F 1798-97(2008)
Axial Torque Gripping Capacity Test for Subassembly	ASTM F 1798-97(2008)
Axial Gripping Capacity Test	ASTM F 1798-97(2008)
Static Compression Test for Subassembly	ASTM F 1717-10
Fatigue Test for Subassembly	ASTM F 1717-10
Static Torsion Test	ASTM F 1717-10
Single Cycle Bend Testing of Metallic Spinal Rods	ASTM F 2193

The results of these mechanical tests demonstrate that the Mikron Spinal Fixation System is as safe, as effective, and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 16, 2013

Mikron Makina Sanayi Ticaret Ltd Sti
% Ohltech Incorporated
Mr. Omar Diker
80 Leicester Way
Chesapeake City, Maryland 21915

Re: K130073
Trade/Device Name: Mikron Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: November 13, 2013
Received: November 15, 2013

Dear Mr. Diker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K130073**

Device Name: Mikron Spinal Fixation System

Indications For Use: **The MSFX Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T1 to S2): severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; spinal stenosis; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).**

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130073